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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,617	06/07/2000	NIGEL J. FORROW	6237.US.01	8065

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EXAMINER
OLSEN, KAJ K

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 09/24/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,617	FORROW ET AL.	
	Examiner	Art Unit	
	Kaj Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-11 and 16-29* is/are pending in the application.

4a) Of the above claim(s) *16,17,19 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11,18,20-25 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. In applicant's remarks on page 5 of the amendment, applicant indicates that claims 16, 17, 19, and 26 have been cancelled. However, applicant has never cancelled these claims, nor has the applicant given the office explicit instructions to cancel those claims. For the purpose of examination, the examiner will treat these claims as if they have been cancelled, but the applicant should respond to this office action by providing unequivocal instructions to cancel the claims in question.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The examiner has withdrawn the previous 112 rejections in view of the applicant's amendment to the claims. However, applicant's amendment of claim 18 renders these claims indefinite. In particular, claim 18 now specifies that R1 and R2 are unsubstituted aromatic or heteroaromatic constituents. However, claim 22 calls for either R1 and/or R2 to be substituted with an alkyl group. How is claim 22 meant to be interpreted when reads away from the claim it depends on? With respect to claim 23, this claim appears to be redundant because claim 18 already specified that R1 and R2 were unsubstituted.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedenmo et al (Analyst, 1996, vol. 121, pp. 1891-1895) in view of Carter et al (USP 5,628,890).

8. Hedenmo discloses a sensor that comprises an active electrode comprising a nicotinamide co-factor dependent enzyme glucose dehydrogenase (GDH), a cofactor of nicotinamide adenine dinucleotide (NAD/NADH), and a mediator containing the molecule 1,10-phenanthroline 5, 6-dione that reads on the claimed formulae (fig. 1). Said electrode is also constructed with filler (carbon) and binder (paraffin oil) ingredients (see "Preparation of Carbon Paste Electrodes", p. 1892). Hedenmo does not explicitly recite the use of the various supports, conductive tracks with reference and counter electrodes, all these specified elements are conventional aspects of

electrode strip construction that are to be used with readout circuitry. Carter shows a protocol for constructing strip sensors and provides a sensor where the location of the sample delivery can be controlled making the sensor easy for an unskilled user to manipulate (see fig. 1 and the associated discussion therein). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Carter for the sensor of Hedenmo because the protocol of Carter is conventional in the art and provides a sensor that is easy for the user to manipulate.

9. Claims 4, 5, 7-11 are rejected under 35 U.S.C. 103(a) as obvious over Hedenmo and Carter as applied to claim 1 above, in further view of Batchelor.

10. With respect to claim 4, the references set forth the limitations of the claim, and Hedenmo further identified that the NAD acts as a coenzyme for over 300 dehydrogenases (see Introduction) but did not explicitly identify the use of HBDH as the cofactor-dependent enzyme. Batchelor teaches an analogous sensor which utilizes the enzyme 3-hydroxybutyrate dehydrogenase which is thereby capable of measuring 3-hydroxybutyrate (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Batchelor for the sensor of Hedenmo and Carter in order to extend the utility of the sensor of Hedenmo to additional compounds such as 3-hydroxybutyrate.

11. With respect to the claims drawn to the method of using the electrode of claim 1 (those limitations not already discussed above), Hedenmo set forth the various components of the sensor and teaches how the various components interact to provide the sensor (fig. 1), but did not explicitly disclose the use of NAD(P). Batchelor teaches in an alternate electrochemical assay that NAD(P) is a alternate form of nicotinamide that finds equivalent utility in the art to that of

NAD (p. 289). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Batchelor for the sensor of Hedenmo and Carter because the substitution of one known nicotinamide for another when the results are not unexpected requires only routine skill in the art.

12. Claims 18, 20, 22-25, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedenmo in view of Gorton et al (USP 4,490,464) and Carter. Gorton was cited by the applicant on 6-30-2003 and is being relied on the first time here. Its use here was necessitated by the applicant's amendment to claim 18 where the specific R1 and R2 conditions set forth in the previous version of the claim (which the examiner found free of the prior art) were amended to read on a much broader category of aromatic and heteroaromatic units.

13. Hedenmo discloses a sensor that comprises an active electrode comprising a nicotinamide co-factor dependent enzyme glucose dehydrogenase (GDH), a cofactor of nicotinamide adenine dinucleotide (NAD/NADH), and a mediator (fig. 1). Said electrode is also constructed with filler (carbon) and binder (paraffin oil) ingredients (see "Preparation of Carbon Paste Electrodes", p. 1892). Hedenmo does not explicitly recite the use of a mediator that reads on the formula of claim 18. Gorton teaches in an alternate electrode relying on nicotinamide reactions that other mediators are known in the art. A number of those mediators read on the formula of claim 18 where R1 and R2 are either substituted or unsubstituted aromatics (see molecule classes 3 and 4 shown in fig. 3), and Gorton teaches that a number of these molecules do not readily dissolve out of the electrode thereby providing enhanced electrode stability (col. 6, lines 36-48). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gorton for the sensor of Hedenmo because

the substitution of one known nictoinamide mediator for another requires only routine skill in the art. In addition, the mediator of Gorton provides a sensor where the mediator does not readily dissolve out providing enhanced electrode stability. Hedenmo and Gorton do not explicitly recite the use of the various supports, conductive tracks with reference and counter electrodes, all these specified elements are conventional aspects of electrode strip construction that are to be used with readout circuitry. Carter shows a protocol for constructing strip sensors and provides a sensor where the location of the sample delivery can be controlled making the sensor easy for an unskilled user to manipulate (see fig. 1 and the associated discussion therein). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Carter for the sensor of Hedenmo and Gorton because the protocol of Carter is conventional in the art and provides a sensor that is easy for the user to manipulate.

14. With respect to the claims drawn to the method of using the electrode of claim 18 (those limitations not already discussed above), Hedenmo and Gorton both set forth the various components of the sensor and teaches how the various components interact to provide the sensor (see Hedenmo fig. 1). In addition, Gorton set forth that NAD(P) is an alternate form of nicotinamide that finds equivalent utility in the art to that of NAD (see reactions in col. 1 and 2).

15. Claims 21 and 28 are rejected under 35 U.S.C. 103(a) as obvious over Hedenmo, Gorton and Carter as applied to claims 18 and 24 above, in further view of Batchelor.

16. With respect to the claims, the references set forth the limitations of the claim, and Hedenmo further identified that the NAD acts as a coenzyme for over 300 dehydrogenases (see Introduction) but did not explicitly identify the use of HBDH as the cofactor-dependent enzyme. Batchelor teaches an analogous sensor which utilizes the enzyme 3-hydroxybutyrate

dehydrogenase which is thereby capable of measuring 3-hydroxybutyrate (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Batchelor for the sensor of Hedenmo, Gorton and Carter in order to extend the utility of the sensor to additional compounds such as 3-hydroxybutyrate.

Response to Arguments

17. Applicant's arguments filed June 27, 2003 have been fully considered but they are not persuasive. With respect to the rejection of claims 1-3, applicant urges that Hedenmo does not disclose a mediator having the formula shown in claim 1. In particular, applicant urges that the compound of Hedenmo is a metal complex where the heteroaromatic rings are attached to a metal atom to form a complex. The examiner fails to appreciate why the fact that Hedenmo is in the form of a metal complex would cause it to read away from the claimed formula of claim 1. Claim 1 is constructed with open language (i.e. the invention "comprises" the claimed formula), and because the claim is constructed with open language, the prior art need not be limited to only those elements set forth by the claim. Because Hedenmo clearly teaches the use of 1,10 phenanthroline-5,6-dione (which reads on the claimed formula), then Hedenmo anticipates that aspect of the invention. The claim never specifies that the mediator represented by that formula can't be a ligand that is complexed to a metal atom.

18. Applicant's arguments concerning the rejections of claims 4, 5, and 7-11 appear to rely on applicant's position that Hedenmo and Carter failed to disclose the subject matter of the claims 1-3. Because the examiner did not find that position persuasive (see above), claims 4, 5, and 7-11 remain rejected for the reasons set forth in the previous and in this office action.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing

of your papers. The fax number for regular communications is (703) 305-3599 and the fax number form after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

Kaj K. Olsen
Patent Examiner
AU 1753
September 17, 2003